UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

RENEE CASTANEDA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 1:20 CV 262 ACL
	)	
SAINT FRANCIS MEDICAL CENTER, et al.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This action is before the Court on Defendant Torax Medical, Inc.'s ("Torax") Motion to Dismiss. (Doc. 28.) Plaintiff opposes the Motion. (Doc. 38.)

Procedural Background

The Complaint states that Plaintiff underwent surgery performed by Dr. Ronald Richmond at Saint Francis Medical Center in December 2018. Dr. Richmond is an employee of Cape Girardeau Surgical Clinic, Inc. ("CGSC"). Plaintiff alleges that Dr. Richmond utilized a defective medical device manufactured by Defendants Torax and Ethicon US, L.L.C. ("Ethicon")[1], such that he suffered significant injury. Specifically, Plaintiff alleges that a defectively manufactured LINX® device was surgically implanted in Plaintiff by Dr. Richmond to control her gastroesophageal reflux disease ("GERD"). Plaintiff claims that Torax was aware of the manufacturing defect in Plaintiff's LINX®, and recalled Plaintiff's LINX®.

Plaintiff sets forth five counts against the remaining defendants: (1) Count I, a negligence claim against Defendants Richmond and CGSC; (2) Count II, a negligence claim against Defendant Saint Francis Medical Center; (3) Count III, a strict liability manufacturing

[1]Plaintiff has voluntarily dismissed Ethicon as a Defendant. (Doc. 43.)

defect claim against Defendant Torax; (4) Count IV, a negligence claim based on a manufacturing defect against Defendant Torax; and (5) Count V, a negligence per se claim based on a manufacturing defect against Defendant Torax. (Doc. 1.)

In the instant Motion to Dismiss, Torax argues that Plaintiff's state law claims asserted against Torax in Counts III, IV, and V are preempted by federal law. Defendant therefore requests that the Court dismiss Plaintiff's claims for failure to state a claim upon which relief can be granted.

Standard

The purpose of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is to test the legal sufficiency of the complaint. When considering a 12(b)(6) motion, the court assumes the factual allegations of a complaint are true and construes them in favor of the plaintiff. *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989). Rule 8(a)(2) provides that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." In *Bell Atlantic Corp. v. Twombly*, the Supreme Court clarified that Rule 8(a)(2) requires complaints to contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." 550 U.S. 544, 555 (2007); accord *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Specifically, to survive a motion to dismiss, a complaint must contain enough factual allegations, accepted as true, to state a claim for relief "that is plausible on its face." *Twombly*, 550 U.S. at 570. The issue in considering such a motion is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of the claim. *See Neitzke*, 490 U.S. at 327.

Background Facts[2]

The LINX® reflux Management System is medical device used to treat patients diagnosed with GERD. LINX® is a titanium bead-and-wire ring surgically implanted around a patient's lower esophageal sphincter ("LES") to augment the LES and prevent acid reflux. The Torax LINX® devices are Class III medical devices subject to a high level of scrutiny under the FDA's Pre-Market Approval ("PMA") process.

In December 2010, Defendant Torax applied for PMA, including its manufacturing process. This approval was granted on March 22, 2012.

On May 31, 2018, Torax initiated a recall of numerous LINX® devices due to "an out of specification condition" which would allow "a bead component to separate from an adjacent wire link." (Doc. 1 at p. 9.) This means that the LINX® device, "normally a continuous loop, would become discontinuous and open due to a defect resulting from improper manufacture." *Id.*

Plaintiff states that, upon information and belief, a 15-bead LINX® was surgically implanted in Plaintiff on December 4, 2018. This LINX® device was subject to the May 31, 2018 recall. Plaintiff alleges that Torax manufactured the LINX® that was implanted in Plaintiff and that the device subsequently failed due to a manufacturing defect. As a result, Plaintiff claims that she suffered incurable vagus nerve damage and damage to her esophagus, and must remain on a liquid diet.

[2]The background facts are taken from Plaintiff's Complaint.

The Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA). *See* 21 U.S.C. § 360c *et seq*. The amendments authorized the FDA to "regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010). Through the amendments, which were a response to proliferation (and frequent failure) of medical devices entering the market, Congress "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (MDA was enacted in "response to the mounting consumer and regulatory concern").

The MDA classifies medical devices into three groups (Classes I, II, and III) based on the degree of risk they pose. In general, Class III devices—as the most dangerous—are subject to the highest level of scrutiny by the FDA. This manifests in a rigorous, comprehensive inquiry called "premarket approval," or PMA. *See Lohr,* 518 U.S. at 477 (noting that it takes the FDA an average of 1,200 hours to review an application for premarket approval). An applicant seeking PMA for a Class III device must supply information to the FDA, including a description of the design, manufacture, and labelling. (Doc. 29 at p. 5.) Following PMA, an applicant must comply with certain FDA requirements and federal regulations, including those set out in 21 C.F.R. Pt. 803, 21 C.F.R. Pt. 820, and 21 U.S.C. §§ 351–52. *Id.*

Federal Preemption

The MDA expressly preempts certain state laws. Subject to some unrelated exceptions, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. § 360k(a). The United States Supreme Court has articulated a two-part test for applying the express preemption principles codified in Section 360k of the MDA. *See Riegel*, 552 U.S. at 321-22. The test requires the court to examine the particular federal laws and regulations applicable to the device in question and compare them to the state claims the plaintiff wishes to bring. First, a court must determine whether "the Federal Government has established requirements" applicable to a particular device. Second, the court must determine whether a plaintiff's claims "are based upon [state] requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." *Id.* If the Court answers both questions in the affirmative, the state laws are expressly preempted by the MDA. *Id.* at 321-23. However, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330.

Premarket approval is a federal "requirement" that meets the first prong of the test for Section 360k preemption. *Riegel*, 552 U.S. at 322–23 (PMA was "specific to individual devices" and "focused on safety, not equivalence."). As for the second prong of the Section 360k preemption test, included in the meaning of "state requirements" subject to federal preemption are common law causes of action, such as negligence and strict liability. *Id.* at 323-244.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court construed § 337(a) of the MDA—which provides that all actions to enforce FDA requirements "shall be by and in the name of the United States"—"as barring suits by private litigants 'for noncompliance with the medical device provisions.'" *In re Medtronic*, 623 F.3d at 1204 (quoting *Buckman*, 531 U.S. at 349 n. 4). The Eighth Circuit Court of Appeals has read *Buckman* and *Riegel* together to create only a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). As such, a plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777) (italics in original).

Discussion

Torax argues that Plaintiff's "manufacturing defect" claims are expressly preempted by the MDA, and her negligence per se claim is impliedly preempted. The parties do not dispute that the first prong of the *Riegel* test is satisfied, as the LINX® device was subjected to PMA and is thus governed by the specific requirements set forth in the PMA. Torax argues that Plaintiff has not pleaded "specific or clear allegations that the LINX® system deviated from its FDA-approved design." (Doc. 29 at p. 18.) Torax further argues that Plaintiff's allegations "are not actually attacking a deviation from the approved design but instead the design itself." *Id.*

Plaintiff responds that she has sufficiently alleged that Torax's conduct violated the FDCA in that it acted negligently in failing to abide by the PMA application and supplements.

Plaintiff relies upon *Warren v. Howmedica Osteonics Corp*, in which this Court[3] held preemption was inappropriate when the plaintiff similarly brought strict liability and negligence claims against the defendant designer and manufacturer of a defective hip device. No. 4:10CV1346, 2010 WL 5093097 (E.D. Mo. Dec. 8, 2010), *adhered to on reconsideration*, 2011 WL 1226975 (E.D. Mo. Mar. 29, 2011). In the alternative, Plaintiff argues that she cannot plead more specific facts until provided with the opportunity to conduct discovery. She therefore requests that the Court grant her leave to amend her complaint to plead more specific facts after participating in discovery.

A. Strict Liability and Negligence (Counts III and IV)

In Count III, Plaintiff alleges that Torax is strictly liable because the device implanted in Plaintiff was "manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval." (Doc. 1 at p. 12.) Plaintiff contends that the LINX® was also manufactured "in deviation of Current Good Manufacturing Practice requirements" and "Missouri law that parallels federal requirements." *Id.* Plaintiff cites seven particular federal regulations it argues Torax violated. *Id.* at p. 13. As a result of Torax's violations of federal regulations, Plaintiff alleges her LINX® was defectively manufactured and failed.

In Count IV, Plaintiff alleges that Torax failed to use ordinary care by various acts and omissions, including the following: (a) failure to manufacture the LINX® consistent with approved manufacturing standards such that it was defective and unreasonably dangerous for its intended use; (b) failure to manufacture the LINX® consistent with approved design such that it

[3]United States Magistrate Judge David D. Noce.

was defective and unreasonably dangerous for its intended use; (c) failure to rest and inspect the device prior to placing it in the stream of commerce in a defective and unreasonably dangerous condition; and (d) failure to prevent the defectively manufactured device from entering the stream of commerce in a defective and unreasonably dangerous condition. *Id.* at p. 14.

In *Hofts v. Howmedica Osteonic Corp.*, 597 F. Supp.2d 830, 837 (S.D. Ind. 2009), the District Court concluded, upon analyzing *Riegel*, that manufacturing defect claims were not preempted by the MDA. *Id*. at 838. The Court explained that the plaintiff was basing claims on allegations that the manufacturer failed to meet the FDA's requirements and not anything else, and that a jury "could find that [the manufacturer] breached the duty of care it owed...by failing to adhere to...manufacturing requirements without imposing different or additional requirements." *Id*. at 837. According to *Hofts*, the plaintiff's claims of manufacturing defect required discovery and were not subject to preemption at the pleading stage. *Id*. at 838. Notably, *Hoft* went on to state:

> If the law were otherwise--if it were as Howmedica argues--then *Riegel* and the MDA would be turned upside down and *Lohr* would be overruled. The MDA, as *Riegel* explained, was intended to protect overall public health and safety by relying on an expert agency to balance overall costs and benefits of medical devices that may do much good and even save lives, but that might not always work as they are intended to work. As applied in *Riegel*, the MDA protects manufacturers who comply with federal requirements from civil liability based on different or additional standards imposed by states (including juries). But if the MDA were construed as Howmedica argues here, the legislation would be transformed in to a grant of immunity from civil liability for manufacturers who violate those same federal requirements. That result was rejected by the Court in *Lohr*, and neither the MDA nor *Riegel* supports it.

Id. at 838-39.

Similarly, this Court has concluded that a plaintiff's manufacturing defect claims survive preemption. In *Warren*, the plaintiffs argued that the defendant manufacturer of a hip device did

not comply with the FDA's PMA standards, resulting in unreasonably dangerous manufacturing defects. 2011 WL 1226975 at *3. Judge Noce applied the Eighth Circuit's decision in *In re Medtronic*, to hold that the plaintiffs' claims survived, because they were based on "'allegations that the product sold by [defendant] was not the product'" approved by the FDA. 2011 WL 1226975 at * 4 (quoting *In re Medtronic, Inc.*, 623 F.3d at 1206. As such, the plaintiffs' allegations were not an attack on the "'risk/benefit analysis'" that led the FDA to approve the Class III product, but rather were allegations that "the defendant's failed to manufacture [the product] in conformity with FDA's PMA specifications, which resulted in a defective device whose manufacture and design were not approved by the FDA." *Id*. Judge Noce further recognized that the "court must be mindful not to hold plaintiffs 'to an impossible pleading standard.'" 2011 WL 1226975 at *5 (quoting *In re Medtronic, Inc*., 623 F.3d at 1206). Thus, the plaintiffs would be "permitted to proceed to discovery to determine which particular PA specifications defendants may have violated in manufacturing [Plaintiff's device]." 2011 WL 1226975 at *5.

The Court finds Judge Noce's reasoning as set forth in *Warren* persuasive. At this very early stage of litigation, Plaintiff has sufficiently alleged claims of manufacturing defects that are not preempted. Defendant argues that Plaintiff's claims fail because they have not alleged any "specific, actual defects." (Doc. 42 at p. 8.) Plaintiff, however, alleged a particular defect or flaw in the manufacturing process. In the section of the Complaint immediately prior to Plaintiff's causes of action entitled "B. Product Defect," Plaintiff states that Torax initiated a recall of numerous LINX® devices on May 31, 2018 due to "an out of specification condition" which would allow "a bead component to separate from an adjacent wire link." (Doc. 1 at p. 9.) Plaintiff further alleges that a 15-bead LINX® was surgically implanted in Plaintiff on December

4, 2018, *which was subject to the recall…*" *Id.* (emphasis added). Plaintiff contends that the device subsequently failed due to the manufacturing defect. *Id.* Notably, Torax does not address Plaintiff's claim regarding the recall.

The claims asserted in Counts III and IV allege *manufacturing* defects, not *design* defects, which are parallel state claims that survive preemption. Simply put, Plaintiff alleges that Torax was negligent in failing to manufacture the LINX® in conformity with the FDA's PMA specifications, such that the product sold by Torax "was not the product" approved by the FDA. *In re Medtronic,* 623 F.3d at 1206.

With regard to Torax's claim of lack of specificity, Plaintiff argues that she does not have access to the PMAs and supplemental PMAs, as Torax and the FDA are in exclusive control of those documents. (Doc. 38 at p. 9.) Plaintiff states that she can provide more specific facts to support her claim after she has the opportunity to engage in discovery. Even though "the precise contours of [her] theory of recovery have not yet been defined," the Court finds Plaintiff's claims sufficiently allege that Torax did not adhere to FDA manufacturing requirements. *Lohr*, 518 U.S. at 495 (199; *see In re Medtronic, Inc.*, 623 F.3d at 1212 ("Manufacturing defect claims are not subject, for example, to the 'particularity' pleading requirements of Rule 9.").

Thus, resolving all disputes in favor of the non-moving party, the Court holds that Plaintiff has plausibly alleged her claims under *Twombly* and *Iqbal* and denies Torax's motion to dismiss for failure to state a claim.

B. Negligence Per Se (Count V)

Torax next argues that Plaintiff's negligence per se claim is impliedly preempted, as it

alleges that Torax breached duties solely created under the FDCA. In its Reply, Torax contends that Plaintiff has tacitly conceded this claim because she did not address it in her Response in opposition to Torax's Motion to Dismiss.

In Count Five, Plaintiff alleges negligence per se based on Torax's violation of "manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval…" (Doc. 1 at p. 15.) This claim escapes express preemption because there are applicable federal regulations for LINX®, and because the claim is a parallel claim.

The Court finds this claim is impliedly preempted "because the applicable standards of care rely on the MDA and, therefore, the existence of this claim exists solely by virtue of the federal requirements." *Zaccarello v. Medtronic, Inc.*, 38 F. Supp.3d 1061, 1071 (W.D. Mo. 2014), citing *Dunbar v. Medtronic, Inc.*, No. 14-1529, 2014 WL 3056026, at *5-6 (C.D. Cal. June 25, 2014), 2014 WL 3056026 at 5-6 (concluding a similar claim is impliedly preempted because "a negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages"). As noted by Torax, Plaintiff has impliedly conceded this claim by failing to address it in her response to Torax's Motion to Dismiss.

Thus, Torax's Motion to Dismiss will be granted as to Count V.

Accordingly,

IT IS HEREBY ORDERED that Defendant Torax Medical, Inc.'s Motion to Dismiss (Doc. 28) is **granted in part and denied in part**. The Motion to Dismiss is **granted** as to Count V and **denied** as to Counts III and IV.

IT IS FURTHER ORDERED that Count V of Plaintiff's Complaint is hereby **dismissed**.

s/*Abbie Crites-Leoni*
ABBIE CRITES-LEONI
UNITED STATES MAGISTRATE JUDGE

Dated this 7th day of July, 2021.